K041659

OCT 2 8 2004

510(k) Summary
C-Boot™ - Lymph and Venous-Insufficiency System

1. Applicant

Name: C-Boot Ltd.
Address: 10 Mahanain st., Haifa 34481, Israel
Phone: +972-54-5369919
Fax: +972-4-9849078

2. Contact Person

Name: Avi Abraham
Company: Avnet Engineering
Address: 8 Marva st., Carmiel 21691, Israel
Phone: +972-54-4949699
Fax: +972-4-9589111
Email: avi_abraham@yahoo.com

3. Date Prepared

Date: June 08,2004

4. Device Name

Common Name: Lymph and Venous-Insufficiency System
Trade Name: C-Boot™

5. Classification

Classification Name: Compressible Limb Sleeve
Device Class: Class II
Panel: Cardiovascular
Product Code: JOW
Regulation Code: 870.5800

6. U.S. Agent

Steve Doppelt
C-Boot® Marketing Consultant
5 Wyndstone Way
Framingham, MA 01701
Phone: 508 820 0707
Fax: 508 820 9971
E-Mail: doppmed@aol.com

7. Predicate Devices

The "C-Boot® Lymph and Venous-Insufficiency System" is substantially equivalent to the commercially available "**WizAir™** Ambulant Pneumatic Compression System" (of MCS), 510(k) number K002287 cleared on 25-Aug-2000;
It is also substantially equivalent to the commercially available **Lympha Press®** (of Mego-Afek), 510(k) number K810338 cleared on 20-Oct-1981.

8. Device Description

C-Boot Ltd. introduces a wearable pneumatic compression technology embodied in a therapeutic boot that has the potential to increase treatment efficacy and improve the quality of life for peripheral vascular and lymph distorders patients.
C-Boot's solution integrates the technological advantages of dynamic compression pumps, that enable preset sequential pressure control to individualize treatment regimes, with the mobility benefit of static compression stockings, that activate the calf muscle pump and strengthened the body's natural tendency to enhance lymphatic and venous return.
The device relates to a self-powered compression devices and methods for promoting circulation and therapeutic compression: It is comprising a pump, a plurality of sleeves or limb massager, which utilizes sequential, cyclical pressure, energy or vector forces, to aid circulation in a body part such as the limbs.
The inflatable sleeves are filled with air by the pump and transmit massaging movement to the vessel walls whenever the patient wearing the device - walks or transmits body's weight from one leg to another.
The pressure generated is a function of the user's body weight and gravitational force. The device provides methods to harness energy generated during movement and weight transfer and uses the energy for compressing to create a massaging effect on the circulation and the muscular-skeletal system.

9. Indications for Use

The C-Boot™ is a prescriptive device that induces controlled compression of the calf, the foot or a combined compression of both.
The C-Boot™ is intended to assist patients, suffering from lymphatic or venous disorders, by treating many conditions including:

a. Prevention of deep vein thrombosis (DVT)
b. Enhancement of blood circulation
c. Reduction of post-operative pain and swelling
d. Reduction of wound-healing time
e. Stasis dermatitis
f. Treatment and assist healing of cutaneous ulceration
g. Venous stasis ulcers
h. Leg ulcers
i. Chronic venous insufficiencies
j. Reduction of edema
k. Prevent pooling of fluids in limbs
l. Lymphedema

10. Contraindications

The C-Boot™ should not be used in the following cases: Advanced peripheral arterial occlusive diseases (calves pain while walking), Decompensated heart disease, Specific phlebitis, Phlegmasia coerulea dolens (swollen blue limb), Diabetic patients with lack of reduced sensation in lower limb or foot, Supportive dermatosis, Intolerance of C-Boot™ fabric, sensory disturbances of the limb, Advance peripheral neuropathy, Primary chronic arthritis.

11. Technological Characteristics and Substantial Equivalence

The C-Boot™ has combined indications of its two (2) predicate devices - WizAir™ and Lympha Press®- into one product. All three (3) devices have **same** shape of surrounding sleeves, inflation mode (sequential), mode of Compression (intermittent), number of Cycles (1-2 per minute) and are made all of basically same materials.

The main differences are the dynamic compression pumps, the overlapping-massaging-movements and the mechanical power source of C-Boot™ (compared to an electrical source of the other predicate devices), which raise neither safety nor effectiveness questions, as C-Boot™ functions within same boundaries of performances.

12. Performance Data

A series of functional, performance and safety testing, including comparative analysis to *Mego-Afek®* and *WizAir™* - demonstrates that **C-Boot™ is substantially equivalent** to *Mego-Afek®* and *WizAir™*, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2004

C-Boot Ltd.
c/o Mr. Avi Abraham
Avnet Engineering
8 Marva Street
Carmiel 21691, Israel

Re: K041659
C-Boot™
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: August 12, 2004
Received: August 16, 2004

Dear Mr. Abraham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. Indications for Use Statement

510(k) Number (if known): **K041659**

Device Name: **C-Boot™**

Indications for Use:
The C-Boot™ is a prescriptive device that induces controlled compression of the calf, the foot or a combined compression of both.
The C-Boot™ is intended to assist patients, suffering from lymphatic or venous disorders, by treating many conditions including:

1. Prevention of deep vein thrombosis (DVT)
2. Enhancement of blood circulation
3. Reduction of post-operative pain and swelling
4. Reduction of wound-healing time
5. Stasis dermatitis
6. Treatment and assist healing of cutaneous ulceration
7. Venous stasis ulcers
8. Leg ulcers
9. Chronic venous insufficiencies
10. Reduction of edema
11. Prevent pooling of fluids in limbs
12. Lymphedema

Prescription Use - √ AND/OR Over-The-Counter Use ____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041659